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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,923	08/12/2004	Melissa Vass	158982 (GEM-0053-P)	4922

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,923	VASS ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-47* is/are pending in the application.

4a) Of the above claim(s) *16-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/12/08 has been entered.

Claim Objections

Claim 47 is objected to because of the following informalities:

In claim 47, "the 3D model" and "the at least three geometric markers and corresponding anatomical landmarks" lack antecedent basis.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 46-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 7286866. Although the conflicting claims are not identical, they are not patentably distinct from each other because using the system for locating and navigating an interventional tool would be an obvious modification.

Claims 1-13 and 46-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 7346381. Although the conflicting claims are not identical, they are not patentably distinct from each other because using the system for locating and navigating an interventional tool would be an obvious modification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 and 46-47 are rejected under 35 U.S.C. 103(a) as being obvious over Okerlund et al. (US 2003/0187358) in view of Vesely et al. (US 6246898).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Okerlund et al. show almost all of the claimed subject matter, except the use of the system for locating and navigating an interventional tool. See e.g., Figure 1, paragraphs [0017]-[0020] and claims 1, 4, 5, 8, 9, and 13. Further regarding claims 6-8 and 13, Okerlund et al. discloses using known post-processing tools for performing advanced vessel analysis and volume rendering such as (AVA) and (CARDIQ) (see paragraphs [0019]-[0020] and GE "CardIQ" and "Advanced Vessel Analysis" product descriptions). Okerlund et al. fail to show the use of the system for locating and navigating an interventional tool.

Vesely et al. disclose a method for carrying out a medical procedure using a three-dimensional tracking and imaging system. Vesely et al. teach locating a navigating an interventional tool using three-dimensional image data (column 15, line 25-column 16, line 53).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the system of Okerlund et al. for locating and navigating an interventional tool, as taught by Vesely et al. The use of imaging systems and tracking systems during interventional procedures is old and well known in the art. Navigation of the interventional tool allows for the physician to accurately move the tool within the patient.

Claims 1-13 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar (US 6650927) in view of Subramanyan et al. (US 6782284), Chen et al. (WO 96/10949), and Vesely et al. (US 6246898).

Keidar discloses a system and method for generating a 3D model for use in cardiac interventional planning procedures (such as ventricular pacing planning or atrial fibrillation planning) including everything except for a database, and operator interface and a post-processing system for inserting a geometrical marker and selecting a viewable parameter. See Figure 1, 6, and 7, and elements 48 and 49.

Subramanyan et al. disclose a method and apparatus for interventional procedure planning (such as placement of a stent) using a user interface (44) and a post-processing system (40, 48) for marker (72, 280) placement and viewable parameter selection (Figures 9-11). Subramanyan also disclose saving a viewable image, anatomical landmark, etc. (34, 46) to be exported to user interface (44). See Figure 1. Subramanyan further disclose wherein the post processing software further performs image rendering (242) and vessel tracking along a centerline (82). It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the user-interface and post-processing software of Subramanyan et al. in the invention of Keidar to enable vascular tracking and visualization in 3D from multiple directions (Subramanyan, column 2, lines 25-27) and to allow intuitive graphical feedback and interaction with the physician (Subramanyan, column 2, lines 39-42) when administering treatment in tricky regions of the heart which are difficult to mentally

visualize (Keidar, column 1, lines 12-27). Furthermore, although Subramanyan disclose saving the image data, a database is not addressed explicitly.

Chen et al. disclose a system and method for anatomical visualization of structures demonstrating that image databases (e.g., 10) are well known and can be used for independently manipulating data and to generate images from a wide variety of viewing positions (see pages 16-18). It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ a database as taught by Chen et al. in the invention of Keidar in view of Subramanyan et al. as is well known in the art and for the above described reasons.

Vesely et al. disclose a method for carrying out a medical procedure using a three-dimensional tracking and imaging system. Vesely et al. teach locating a navigating an interventional tool using three-dimensional image data. The tool contains several transducers which can be tracked. Additional reference transducers are also located on or in the patient (anatomic landmarks). The tool can be moved within the patient and 3-D coordinate data can be collected of the patient's organ. These reference transducers (markers) can be used to register 3-D image data of the patient with the coordinate system. This results in a model of the patient's organ and the tool, which the physician can then accurately guide within the body (column 15, line 25-column 16, line 53).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the combined system of Keidar et al., Subramanyan et al., and Chen et al. for location and navigation of an interventional tool as taught by

Vesely et al. The use of imaging systems and tracking systems during interventional procedures is old and well known in the art. Navigation of the interventional tool allows for the physician to accurately move the tool within the patient. The imaging data must be registered with the position of the tool for the data to aid the physician in guiding the tool, and the use of markers is a common technique. Other techniques for registering the image data and position data are also well known and would be suitable for use in such systems.

Response to Arguments

Applicant's arguments with respect to claims 1-13 and 46-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737